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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,580	04/12/2004	Scott A. Entenman	AUGA07000021	2643

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/822,580	Applicant(s) ENTENMAN ET AL.	
	Examiner Laura C. Schell	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner how a "handle formed in the fluid container *against* the stiffener" can be considered a handle. If the "handle" is formed against the stiffener, the only components of Applicant's invention that are formed against the stiffener, are the two sheets (20) and (22). This wording of the claim is unclear, because presently, the claim reads that the thin sheets are what form the handle, as they are the only things "against the stiffener".

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 13-17, 19, 20, 27, 29-31 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Jusiak et al. (US Patent No. 6,901,216). Jusiak discloses a fluid warming cassette (Fig. 1) comprising: a first sheet (Fig. 2, 32) and a second sheet (34), made from polyethylene, joined together to form a fluid container with a periphery, the periphery having a proximal end, a distal end and first and second

Art Unit: 3767

sides there between; a fluid channel (Fig. 1, 21) in the fluid container between the first sheet and the second sheet; first and second rails (30a and 30b), inside the periphery, near the first and second sides, respectively; and a planar stiffener (42), separate from the first and second rails, disposed between the first sheet and the second sheet (col. 3, lines 27-40 and lines 47-53), and between the first and second rails, near the proximal end.

Jusiak further discloses that the first and second rails can be made of different shapes and thus have a multilateral cross-section (col. 3, lines 59-60) and would have a first surface supporting an arch of the first sheet. Jusiak also discloses that the stiffener has a first elongate portion extending between the first and second rails (Fig. 3, 42) and a second portion (Fig. 4b, the portion that curves out) protruding from the first portion in the direction of the distal end. Jusiak also discloses that the rails have shapes for keying the insertion of the cassette into a warming unit (col. 3, lines 59-61). Jusiak further discloses that the serpentine fluid channel (21) is disposed between the first and second rails (30a and 30b). Jusiak further discloses that the stiffener forms a handle portion (either 42 or the portion curving out in Fig. 4b could be used as a handle). Jusiak further discloses that the cassette has a label surface (66). Jusiak also discloses first (24) and second (26) ports in fluid communication with the fluid channel (21). Jusiak further discloses that the rails can be made of any conventional material, such as plastic or metal (col. 3, lines 63-65). Jusiak also discloses that the stiffener can be made of any polymeric material or metal (col. 4, lines 31-36).

Jusiak further discloses a fluid warming cassette comprising: a flexible fluid container with two edges and two ends (Fig. 1); a fluid channel (21) in the fluid container; first and second rails (30a and 30b) disposed in the fluid container, near first and second edges of the fluid container, respectively; and a handle portion (20) formed near an end of the fluid container by sandwiching a planar piece in the fluid container (col. 4, lines 37-41).

Jusiak also discloses the process including: positioning a first and second rail parallel to each other enclosed by a base sheet and a cover sheet, and positioning a planar stiffener at an end of the sheets and between the sheets and rails and then joining the base and cover sheet to enclose the rails and the planar stiffener and forming a fluid channel (col. 3, lines 21-26, 47-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12, 28, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Tousignant et al. (US Patent No. 5,205,348). Jusiak discloses the device substantially as claimed including ports, however, Jusiak does not disclose expressly that the ports are disposed perpendicularly to the fluid container or that they constitute insertion stops. Tousignant discloses two ports (Figs. 4-6) that are

perpendicular to the fluid container. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the perpendicular ports as taught by Tousignant in order to provide ports that the sheets/films can seal around, rather than sealing to the ports individually as taught by Jusiak; by sealing around the ports, as taught by Tousignant, the ports come up perpendicularly through the sheet and there is no risk of the sealing engagement coming undone by the ports sliding out of position (col. 6, line 63 through col. 7, line 18).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Bakke (US Patent No. 6,608,968). Jusiak discloses the device substantially as claimed except for the stiffener being made of cardboard or cardstock. Bakke, however, discloses a fluid-warming envelope (Fig. 4, 16) with a paperboard stiffener (26) to aid in inserting the envelope into the warmer. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the paperboard stiffener as taught by Bakke, in order to provide another inexpensive material for use as a stiffener with the cassette.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Greenblatt (US Patent No. 4,707,587). Jusiak discloses the device substantially as claimed except for each sheet being made of a plurality of layers. Greenblatt, however, discloses a fluid warming jacket (Figs. 7 and 8, 7) in which each of the first and second sheets is made of a plurality of layers. Each sheet is made of an inner layer of plastic and an outer layer of aluminum, which are laminated together (col. 2, line 66 through col. 3, line 4). Thus, the inner layer (plastic) has a lower melting point

than the outer layer (aluminum). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the laminated layers of Greenblatt in order to provide a jacket with a conductive layer and a non-reactive layer that contacts the blood.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Tousignant and further in view of Kujawski et al. (US Patent No. 4,568,330) and further in view of Lundquist (US Patent No. 4,227,525). Jusiak in view of Tousignant discloses the kit substantially as claimed including: a fluid warming cassette with fluid channel, rails, planar stiffener, and inlet and outlet ports perpendicular to the warming cassette. Jusiak in view of Tousignant, however, does not disclose expressly inlet and outlet lines, a drip chamber or a bubble trap. Kujawski discloses a fluid chilling chamber (Fig. 1, 54) which has an inlet line (52) including an inlet end (44) for receiving fluid from sources, a drip chamber (42) with an inlet coupled to the first end and an outlet coupled to the inlet port (where 52 connects to 54); and an outlet line (56) including a bubble trap (144 and 146) with an inlet coupled to the outlet port (where 54 connects to 56) and an outlet (64), and an outlet end (72) for delivering warmed fluid. Kujawski, however, does not disclose an injection site. Lundquist discloses an infusion set with an injection site. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak in view of Tousignant with the inlet and outlet lines, drip chamber and bubble trap as taught by Kujawski and the injection site as taught by Lundquist, in order to provide a kit that is ready for use with a patient and infusion source.

Response to Arguments

Applicant's arguments filed 5/24/2006 have been fully considered but they are not persuasive.

First, in response to the last rejection of claims 1, 4-10, 13-17, 19, 20 and 27 being rejected under USC 103(a) by Jusiak (US 6,901,216) in view of Jordan (US Patent No. 5,875,282), this was an error on the Examiner's part. As the remainder of the rejection reads, and Applicant pointed out, Jordan was not brought into the rejection. The correct rejection, appearing now in this office action, is a rejection under USC 102(e) by Jusiak (US Patent No. 6,901,216).

In response to Applicant's arguments regarding claim 1, element (42) is a planar piece, that despite its size, inherently acts as a stiffener, not only by stiffening the area that (42) spans between the two sheets, but it also stiffens the connection between (26) and (24). Furthermore, it is located between the rails (30a and 30b). Additionally, in response to the arguments that (42) is not located between the two sheets, col. 3, lines 27-40 and lines 47-53 disclose that the inlet (24) and outlet (26) form a system (36), including connecting piece (42) that is advantageous because "the system has more planar space in which the films 32, 34 can seal around" (col. 3, lines 36-37). This unquestionably means that the system (36) which includes (42) would be positioned and located between the two sheets, otherwise Jusiak could not claim that both films 32 and 34 *seal around* the system. Furthermore, Jusiak discloses that the system (36), which again includes (42), is "positioned between the films 32, 34" (col. 3, lines 47-49).

In response to Applicant's arguments regarding claim 4, Fig. 1 discloses that the planar stiffener (42) is an elongate portion, wherein the definition of the word "elongate", according to the American Heritage dictionary online

{<http://www.bartleby.com/61/56/E0095600.html>} is: "having more length than width", which clearly describes element 42. Furthermore, (42) is indeed located between the rails (30a and 30b), as the claim does not specify that the elongate portion is located between the rails and abuts against each rail, or comes into contact with each rail. Additionally, since the first elongate portion of the stiffener is element (42), and Jusiak discloses that the system (36), which includes (26, 24 and 42), the second portion can be either (26) or (24), portions of which lie within the two sheets, both of which protrude from the first portion (42) in the direction of the distal end (end that includes element 30c). Both (24) and (26) can be part of the stiffener, as Jusiak discloses that "the system 36 has more planar space in which the films 32, 34 can seal around" and therefore is part of the "planar" stiffener.

In response to Applicant's arguments regarding claims 29-31, the handle portion (20), is in fact a planar piece sandwiched between the two films. Col. 4, lines 37-41 disclose that the planar piece is sealed to the films in the same manner that the rails (30a and 30b) are sealed, wherein the rails are sealed between the two films as supported by Fig. 2 showing a cross-section with the two rails between the two films (32 and 34). Furthermore, col. 3, lines 47-52 discloses that the rail system is placed between the two films before the films are sealed.

In response to arguments directed towards claims 11, 12, 28, 32 and 33, see the above modified rejection.

In response to arguments directed towards claim 18, Bakke uses a paperboard inserter (26) as a means for stiffening the cassette (col. 2, lines 49-53) because the cassette of Bakke does not have support structures of other stiff plastic cassettes. Therefore using the material paperboard, would have been obvious in view of the purpose of Bakke using this material. Furthermore, using cardboard or cardstock would have been obvious as it is a mere substitution in material, which serves the same purpose. Additionally, Bakke's end that includes element (26) can be considered the proximal end, as Applicant does not include claim language specifying structure that defines which end is the proximal end. Further, element (26) can be considered the proximal end as this is the end which is grasped by the user to insert the cassette, and Applicant's invention places the handle on the same end, and is grasped by the user to insert the cassette in the same manner.

In response to arguments directed towards claims 21-26, Jusiak discloses that Greenblatt's cassette would be undesirable due to the holes on the sides of the cassette (col. 1, lines 34-35) and the structure of the inlet and outlet, however, no discussion is made as to the plurality of layers of the sheets that Greenblatt uses, and therefore does not teach away from using Greenblatt with regard to that aspect of Greenblatt. It would still be obvious to have modified Jusiak with the layered sheets as taught by Greenblatt.

In response to arguments directed towards claim 35, Kujawski does disclose a system for cooling the drugs, however, Kujawski is brought in as a reference for

Art Unit: 3767

disclosing the inlet/outlet lines, bubble trap and drip chamber, all of which do not change function whether fluid is warmed or cooled, and are standard additions to infusion sets.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

